

AMENDMENTS TO THE CLAIMS

The following listing of the claims replaces all prior versions and listing of the claims for this matter. Within this listing of the claims, claims 1-28, 36, and 62-73 are pending; claim 1 is currently amended; claims 29-35 and 37 are withdrawn from consideration as drawn to a non-elected species; and claims 38-61 are canceled as a result of a restriction requirement.

1. **(Currently amended)** A sustained release oral dosage form for delivering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient with restricted delivery to the lower intestinal tract and colon, the dosage form comprising a therapeutically effective amount of the pharmacologically active agent incorporated in a matrix of at least one biocompatible, hydrophilic polymer that:

(a) swells unrestrained dimensionally in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention of the dosage form in the stomach of a patient in whom the fed mode has been induced; and

(b) gradually erodes within the gastrointestinal tract over a determinable time period, wherein an optimal rate of release of the active agent from the dosage form is determined by ~~taking~~ adjusting the ratio of the erosion rate ER obtained *in vitro* for the dosage form to the dissolution rate DR obtained *in vitro* for the dosage form such that the ratio of ER to DR in the dosage form is approximately 1.2:1 to approximately 5:1.

2. **(Original)** The dosage form of claim 1, wherein the ratio of ER to DR is in the range of approximately 1.2:1 to approximately 3:1.

3. **(Original)** The dosage form of claim 2, wherein the ratio of ER to DR is in the range of approximately 1.3:1 to approximately 2:1.

4. **(Original)** The dosage form of claim 3, wherein the ratio of ER to DR is in the range of approximately 1.5:1 to approximately 2:1.

5. **(Original)** The dosage form of claim 1, wherein the therapeutically effective amount of the active agent is in the range of about 0.01% to 80% by volume.

6. **(Original)** The dosage form of claim 1, wherein the therapeutically effective amount of the active agent represents at least 60% of the dosage form by volume.

7. **(Original)** The dosage form of claim 6, wherein the therapeutically effective amount of the active agent represents approximately 60% to 80% of the dosage form by volume.

8. **(Original)** The dosage form of claim 1, wherein following oral administration to a patient in the fed mode, the dosage form is retained in the upper gastrointestinal tract for a time period of about 2 to 12 hours.

9. **(Original)** The dosage form of claim 8, wherein following oral administration to a patient in the fed mode, the dosage form is retained in the upper gastrointestinal tract for a time period of about 4 to 9 hours.

10. **(Original)** The dosage form of claim 8, wherein at least 75 wt.% of the active agent is released within the time period.

11. **(Original)** The dosage form of claim 10, wherein at least 85 wt.% of the active agent is released within the time period.

12. **(Original)** The dosage form of claim 9, wherein at least 75 wt.% of the active agent is released within the time period.

13. **(Original)** The dosage form of claim 12, wherein at least 85 wt.% of the active agent is released within the time period.

14. **(Original)** The dosage form of claim 1, wherein at least 90 wt.% of the dosage form disintegrates *in vitro* in the range of about 1.5 to about 12 hours using USP disintegration test equipment, and at least 90% of the drug is released *in vitro* in less than 25 hours using USP dissolution test equipment.

15. **(Original)** The dosage form of claim 14, wherein at least 90 wt.% of the dosage form disintegrates *in vitro* in the range of about 1.5 to about 10 hours using USP disintegration test equipment,

and at least 90% of the drug is released *in vitro* in less than 20 hours using USP dissolution test equipment.

16. **(Original)** The dosage form of claim 1, wherein at least 90 wt.% of the dosage form disintegrates *in vitro* in the range of about 1.5 to about 9 hours using USP disintegration test equipment, and at least 90% of the drug is released *in vitro* in less than 16 hours using USP dissolution test equipment.

17. **(Original)** The dosage form of claim 1, wherein the aqueous solubility of the active agent decreases with increasing pH.

18. **(Original)** The dosage form of claim 17, wherein the active agent is slightly soluble to soluble in water at a pH in the range of 1 to 4, but becomes substantially insoluble in water at a pH above about 5.

19. **(Original)** The dosage form of claim 18, wherein the active agent is slightly soluble to soluble in water at a pH in the range of 1 to 2, but becomes substantially insoluble in water at a pH in the range of about 5 to 8.

20. **(Original)** The dosage form of claim 19, wherein the active agent is slightly soluble in water at a pH in the range of 1 to 2, but becomes substantially insoluble in water at a pH in the range of about 5 to 7.5.

21. **(Original)** The dosage form of claim 1, wherein the at least one biocompatible hydrophilic polymer is selected from the group consisting of: polyalkylene oxides; cellulosic polymers; acrylic acid and methacrylic acid polymers, and esters thereof; maleic anhydride polymers; polymaleic acid; poly(acrylamides); poly(olefinic alcohol)s; poly(N-vinyl lactams); polyols; polyoxyethylated saccharides; polyoxazolines; polyvinylamines; polyvinylacetates; polyimines; starch and starch-based polymers; polyurethane hydrogels; chitosan; polysaccharide gums; zein; shellac-based polymers; and copolymers and mixtures thereof.

22. **(Original)** The dosage form of claim 21, wherein the at least one biocompatible hydrophilic polymer is a polyalkylene oxide polymer or copolymer, a cellulosic polymer, a gum, or a mixture thereof.

23. **(Original)** The dosage form of claim 22, wherein the at least one biocompatible hydrophilic polymer is a polyalkylene oxide selected from the group consisting of poly(ethylene oxide), poly(ethylene oxide-co-propylene oxide), and mixtures thereof.

24. **(Original)** The dosage form of claim 23, wherein the at least one biocompatible hydrophilic polymer is poly(ethylene oxide) optionally in admixture with poly(ethylene oxide-co-propylene oxide).

25. **(Original)** The dosage form of claim 1, wherein the at least one biocompatible hydrophilic polymer has a number average molecular weight in the range of approximately 5,000 and 20,000,000.

26. **(Original)** The dosage form of claim 1, wherein the active agent is ciprofloxacin or an acid addition salt thereof.

27. **(Original)** The dosage form of claim 26, wherein the active agent is ciprofloxacin hydrochloride.

28. **(Original)** The dosage form of claim 1, wherein the active agent is a *Helicobacter pylori* eradicator.

29. **(Withdrawn)** The dosage form of claim 28, wherein said eradicator is selected from the group consisting of bismuth subsalicylate, bismuth citrate, amoxicillin, tetracycline, minocycline, doxycycline, clarithromycin, thiamphenicol, metronidazole, omeprazole, ranitidine, cimetidine, famotidine and combinations thereof.

30. **(Withdrawn)** The dosage form of claim 29, wherein said eradicator is bismuth subsalicylate.

31. **(Withdrawn)** The dosage form of claim 1, wherein the active agent is contained within a vesicle.

32. **(Withdrawn)** The dosage form of claim 31, wherein the vesicle is selected from the group consisting of liposomes, nanoparticles, proteinoid and amino acid microspheres, and pharmacosomes.

33. **(Withdrawn)** The dosage form of claim 32, wherein the vesicle is comprised of a nanoparticle.

34. **(Withdrawn)** The dosage form of claim 33, wherein the nanoparticle is a nanosphere, a nanocrystal, or a nanocapsule.

35. **(Withdrawn)** The dosage form of claim 31, wherein the active agent is water soluble but rendered sparingly water soluble by said vesicle.

36. **(Original)** The dosage form of claim 1, wherein the dosage form is comprised of a tablet.

37. **(Withdrawn)** The dosage form of claim 1, wherein the dosage form is comprised of a capsule.

38-61. **(Canceled)**

62. **(Previously presented)** The dosage form of claim 1, wherein the ER is determined by using a disintegration test.

63. **(Previously presented)** The dosage form of claim 1, wherein the DR is determined by using a dissolution test.

64. **(Previously presented)** The dosage form of claim 63, wherein the dissolution test is conducted with USP dissolution test equipment.

65. **(Previously presented)** The dosage form of claim 65, wherein the disintegration test is conducted with USP disintegration test equipment.

66. **(Previously presented)** A sustained release oral dosage form for delivering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient with restricted delivery to the lower intestinal tract and colon, the dosage form comprising a therapeutically effective amount of the pharmacologically active agent incorporated in a matrix of at least one biocompatible, hydrophilic polymer that:

(a) swells in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention of the dosage form in the stomach of a patient in whom the fed mode has been induced; and

(b) gradually erodes within the gastrointestinal tract over a determinable time period, wherein the ratio of the erosion rate ER obtained *in vitro* for the dosage form using USP disintegration test equipment to the dissolution rate DR obtained *in vitro* for the dosage form using USP dissolution test equipment is in the ratio of ER to DR is approximately 1.2:1 to approximately 5:1, and further wherein the dosage form is a tablet with at least two layers wherein at least one of the at least two layers contains the active agent and is comprised of a polymer that is erodible.

67. **(Previously presented)** The dosage form of claim 66, wherein at least one of the at least two layers is a swellable layer.

68. **(Previously presented)** The dosage form of claim 67, wherein the swellable layer also contains the active agent.

69. **(Previously presented)** The dosage form of claim 66, having three layers.

70. **(Previously presented)** The dosage form of claim 69, wherein two of the three layers are erodible layers containing the active agent.

71. **(Previously presented)** The dosage form of claim 70, wherein the two erodible layers are outer layers of the dosage form.

72. **(Previously presented)** The dosage form of claim 71, wherein the middle layer of the dosage form is a swellable layer.

73. **(Previously presented)** The dosage form of claim 72, wherein the swellable layer also contains the active agent.